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Michael L Goldman
Nixon Peabody
Clinton Square
PO Box 31051
Rochester, NY 14603

EXAMINER	
NICKOL, GARY B	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/830,520
Filing Date: July 20, 2001
Appellant(s): HEMPSTEAD ET AL.

Michael L. Goldman
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 18, 2005.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of invention contained in the brief is correct.

(6) Grounds of Rejection/Arguments

35 U.S.C. 102(e): Claims 7, 9-10, 18-19, 55, and 59-60 remain rejected under 35 U.S.C. 102(e) as being anticipated by Alps *et al.* (US Patent No. 5,733,871, March 1995).

Appellants argue that Alps *et al.* does not anticipate the claimed invention (Brief, page 6) in that Alps' method of treating neuronal damage would not have suggested to scientists in the field that the trk receptor ligands, brain derived neurotrophic factor (BDNF), NT-3, or NT-4 "would be useful" in inducing angiogenesis. Appellants further note that nowhere does Alps disclose inducing angiogenesis in a patient that has cardiac ischemia by administering a trk receptor ligand in an amount effective to induce angiogenesis and to treat cardiac ischemia or inducing angiogenesis in a patient that has a vascular disorder by administering a trk receptor ligand in amount effective to induce angiogenesis and to treat the vascular disorder. This argument has been carefully considered but is not found relevant. While Alps *et al.* do not explicitly teach the induction of angiogenesis, the reference teaches the intravenous administration of BDNF, NT-3, or NT-4 (see abstract) for the treatment of strokes and cardiac arrests (column 4, line 55), which as set forth previously, would inherently induce angiogenesis. To be anticipatory under 35 U.S.C. 102, a single prior art reference must disclose, either expressly or *inherently*, each limitation of the claim. To the extent that the limitations of all of the claims are anticipated, appellant's brief only concentrates on the fact that the prior art does not explicitly teach the induction of "angiogenesis" with a trk receptor ligand. Thus, while appellants argue that some of the examples and models used by Alps such as focal and global ischemia (Brief, bottom of page 6) only indicates that Alps seeks to treat neuronal damage with BDNF, NT-3, or NT-4; or that it was <u>not</u> known at the time of filing that BDNF, NT-3, or NT-4 had the ability to promote blood vessel formation (Brief, bottom of page 7) is largely irrelevant to the issues of inherency under 35 U.S.C. 102. First, the claiming of a new use, new function or

unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Secondly, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure *at the time of invention*, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

Appellants also argue (Brief, page 9) that the Examiner improperly relied on the doctrine of inherency. Appellants argue (Brief, page 9, 3rd paragraph) that nowhere does Alps teach inducing angiogenesis in a patient that has cardiac ischemia or in a patient that has a vascular disorder by administering BDNF, NT-3, or NT-4. Appellants argue that all Alps does is prevent neuronal damage. Appellants also argue that the examples of Alps all involve the treatment of global or focal ischemic animal models with bFGF, NGF, or CNTF, which either artificially induce neuronal damage by reducing the flow of oxygen or permanently occlude a blood vessel. Appellants argue (Brief, page 10) that these animal models do not treat the ischemic event but only the symptoms caused in the animal models. Appellants argue that because said animal models do not involve the claimed pool of patients, the claimed trk receptor ligands, nor the desired outcome, "the examples of this reference are certainly not anticipatory". This argument has been considered but is not found persuasive because appellants have only directed their argument to a particular disclosed example. On the contrary, patents, as references are relevant as prior art for all they contain (MPEP 2123), and disclosed examples or preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi,* 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

Appellants further argue (Brief, page 10, 2nd paragraph) that to the extent that Alps discusses treatment of patients, as opposed to animal models, it is all with regard to the treatment of neuronal damage and always in the prophetic sense. Appellants argue that such discussion involves the proposed treatment of neuronal damage in patients caused by cerebral arterial occlusion as opposed to what appellants claim –i.e. inducing angiogenesis to treat cardiac ischemia or a vascular disease. This argument has been considered but is not found persuasive. The prior art's treatment of patients in the prophetic sense still renders the claims anticipatory. Furthermore, although the reference teaches treating neuronal damage (abstract), appellants have failed to clearly contrast the claimed patient population from those patients treated in the teachings of Alps. As set forth in previous actions, Alps clearly teaches that the methods and compositions are suitable for the treatment of stroke or cardiac arrest, which results in ischemic or hypoxic damage or neurodegeneration. Appellants do not distinguish strokes and cardiac arrests from the claimed "cardiac ischemia" or "vascular disorder".

Appellants further assert (Brief, pages 10-11) that a particular passage from the decision made in *Rosco, Inc. v. Mirror Lite Co.,* is relevant to the extent that the missing element must be recognized by those skilled in the art reading the cited art. Appellants note that the previously filed Declaration (07-26-04) by Dr. Madri clearly pointed out that those of ordinary skill in the art would not have recognized Alps as teaching that BDNF, NT-3, and NT-4 are useful in promoting angiogenesis. This argument has been considered but is not found persuasive as the decision regarding inherency was based on missing "descriptive" material or element in a design patent that does not clearly parallel the current situation. To reiterate, the current claims and the cited art teach administering the same compound to treat the same group of patients. Thus, it

does not appear that the claim language or limitation results in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). And while angiogenesis is not explicitly taught in the prior art, it is a well-defined natural, biological process (see Brief, page 4) that occurs in response to many different growth factors.

Appellants further argue that the claimed invention is directed to a patentable new use (Brief, pages 11-12) because the use of BDNF, NT-3, or NT-4 to induce angiogenesis and treat either a vascular disorder or cardiac ischemia is not inherently disclosed in Alps. Appellants argue that pursant to 35 USC 101, patent protection is available for any new or useful process, provided the other conditions for patentability are met wherein such a process is defined under 35 USC 100(b) as encompassing "a new use of a known....composition of matter, or material". This argument has been considered but is not relevant because the issues regarding the usefulness of the currently claimed invention (35 U.S.C. 101) have not been raised.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER

Gary B. Nickol
June 27, 2005

Conferees
Jeffrey Siew
Christina Chan

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
6/27/05

Michael L Goldman
Nixon Peabody
Clinton Square
PO Box 31051
Rochester, NY 14603

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600